Division of Medical Assistance **General Clinical Policy No. A-3**
Prior Authorization for Outpatient **Effective Date: March 4, 2002**
Pharmacy Point of Sale Medications

1.0 Policy Statement

This policy applies to designated drugs requiring prior authorization through Medicaid. Prior authorization is the mandatory advance approval by Medicaid for the use of selected high-cost, high-risk, and high-use medications. Prior authorization for designated drugs is linked to specific, pre-existing criteria for appropriate use of the medication such as diagnosis, duration of therapy, dosage, risk-benefit of treatment or other patient-specific characteristics such as prior treatment failure, etc.

2.0 Policy Guidelines

2.1 Identification of Candidate Drugs for Prior Authorization Process

2.1.1 High-Risk, High-Cost, High-Use

A drug may be considered for prior authorization if:

- The medication is being used as first line therapy where there are similarly efficacious, effective, and safe drugs available at substantially less cost.
- The drug is subject to abuse or fraudulent use.
- The medication is so costly that advance assurance of indication for use is desirable rather than retrospective analysis.
- The increase in usage of the drug is far greater than would be expected based on clinical evidence of efficacy.
- Guidelines for appropriate use are complex and/or require yearly seasonal adjustment.
- There is evidence that the medication is being used inappropriately.

2.1.3 Documentation of Baseline Use/Need in North Carolina

Drugs being considered for prior authorization are evaluated, as appropriate, by examining N.C. Medicaid recipient data relative to :

- Age group, benefit groups, race/ethnicity, specialty of prescriber
- Diagnoses of recipients
- Length of therapy, number of prescriptions, varying dosages per patient
- Rate of increase in use compared to similar drugs or drug classes
- Annual costs of care or costs of an episode of care

2.1.4 Additional Questions to Consider

- Can clear criteria be written to indicate an approved use of the medication?
- Can an anticipated programmatic outcome and magnitude of desired change be identified?
- Will adding the drug to the prior authorization list place an undue hardship on one particular provider group? (This determination will be based in part on the number and type of drugs already prior authorized.)
- Have adverse health outcomes from prior authorization either (i) not been shown in previous studies or (ii) anticipated to be negligible?
- Can parameters to monitor desired outcomes and unintended consequences from prior authorization be specified?

2.2 Information Sources to Develop Criteria

Criteria will be developed considering as many of the following sources as are applicable and/or available for a particular drug in order for the Pharmacy and Therapeutics Committee (Committee) of the N.C. Physicians Advisory Group (NCPAG) to understand the appropriate use of the drug and any national/local standards of care.

An adequate literature search will consist of:

- FDA labeling
- Systemic reviews on use of the drug (e.g., AHRQ, Cochrane, NLM-indexed articles)
- Peer-reviewed literature for adequate documentation of off-label uses and nationally specified compendia for off-label use (e.g., USP DI, Micromedix, AHFS)
- Any articles on gender and/or racial differences relevant to appropriate use of the drug
- Clinical practice guidelines published by specialty societies
- Head to head studies on use of the drug compared to alternatives (drug and non-drug)

Additional sources of information:

- Medicare guidelines for use of a drug.
- Examples of criteria from other Medicaid states and local health plans. (The intent of these benchmarks is to help evaluate the criteria in reference to populations similar to N.C. Medicaid as well as ensuring that the Medicaid population has parity with local standards of care.)
- Outcome studies related to administrative controls for a drug.
- Subspecialty and specialty input at all stages of criteria development.

Copies of resource materials are provided to the Committee at least two weeks prior to meetings. In the course of the evaluation, the Committee may need to address the issues of whether this is an appropriate candidate drug and may need to review additional information on an iterative process.

2.3 Draft and Final Criteria

The Committee reviews the materials and drafts a recommendation to the NCPAG. The draft recommendation must include:

- The drug or drugs including brand and generic names, formulation under prior authorization, and others that may not be included.
- Specific criteria for approved use including whether a patient taking the drug before the prior authorization should be subject to the authorization (grandfathering) and duration of the prior authorization for an individual patient
- Clearly stated and implementable criteria (e.g., use of a specific age cut off rather than use of terms such as “old” or “young”).
- Clearly stated restrictions (e.g., criterion that does not include dosage restrictions should not be restricted on this basis).
- Approved standard operating procedure/protocol for the pharmacy benefits manager (PBM) including referral process for appeal and any suggestions they plan to offer physicians.
- The specific issue triggering the suggestion for prior authorization.

- A suggested duration of prior authorization prior to monitoring programmatic and patient outcomes.

2.4 Ongoing Monitoring of Prior Authorization Effects

Each drug that is on the prior authorization list is monitored to determine the effect of the prior authorization process on utilization and appropriate use. The frequency of the monitoring is determined by the Committee.

Monitoring includes usage by age, eligibility class, and diagnosis, etc. (also sex, race, and ethnicity if available) as outlined in the development of the prior authorization.

A report from the PBM of the number of approvals, denials, overrides, reasons for denial or override, and the number and nature of appeals is reviewed quarterly. Additional detail may be specified by the Committee or by the Division of Medical Assistance.

Records are kept for each prior approval as to chronological history including: date of last literature review, initiation date, date of sub-specialist review, date of NCPAG approval, date of implementation, dates of re-review and any major changes, and next date for Committee review. Minor revisions to the prior authorization list will be accomplished by the Committee and given as information to the NCPAG.

2.5 Removing a Drug from the Prior Authorization Process

If monitoring indicates that a drug should be considered for removal from the prior authorization process, the Committee assesses factors relative to utilization, cost effectiveness, efficacy, and the overall effect of removing the prior authorization requirement. The Committee makes recommendations based on findings to the NCPAG.

The following examples represent reasons to consider removal of a drug from the prior authorization list:

- After 6 months of the prior authorization process, there is no change in utilization and a less than 3 percent denial rate. This would indicate that the use of the drug met criteria prior to prior authorization.
- After initial desired impact of the prior authorization process, there is 6 continuous months of minimal change in utilization. This would indicate maximum effect and provider prescription change achieved. If the drug is removed, utilization should be monitored for 1 year to assure the change is maintained.
- Unintended negative health outcomes or negative effects on one patient group or eligibility group.
- The cost of the prior authorization is greater than the cost savings or improvement in quality realized by its use.
- There is new evidence to suggest that the conditions represented in constructing the original prior authorization have changed substantially (e.g., a new indication is approved, the cost of the drug changes, etc.).

3.0 Policy Implementation/Revision Information

Original Effective Date: March 4, 2002

Revision Information:

Date	Section Revised	Change